



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: Composition and Methods for Delivering Inhibitory Oligonucleotides for the Treatment of Pancreatic Cancer

AGENCY: National Institutes of Health

ACTION: Notice.

SUMMARY: The National Institute on Aging, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the U.S. Patents and Patent Applications listed in the Supplementary Information section of this notice to VeriLuce Therapeutics (“VLT”) located in Toronto, ON, Canada.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute’s Technology Transfer Center on or before [INSERT DATE 15 DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: Surekha Vathyam, Ph.D., Senior Technology Transfer Manager, NCI Technology Transfer Center, 9609 Medical Center Drive, RM 1E530 MSC 9702, Bethesda, MD 20892-9702 (for business mail), Rockville, MD 20850-9702 Telephone: (240)-276-5530; Facsimile: (240)-276-5504 E-mail: vathyams@mail.nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

- United States Provisional Patent Application No. 61/045,088, filed April 15, 2008, titled “Composition and methods for delivering inhibitory oligonucleotides”, [HHS Reference No. E-051-2008/0-US-01], status: expired;
- International Patent Application No. PCT/US2009/040607, filed April 15, 2009, titled “Composition and methods for delivering inhibitory oligonucleotides”, [HHS Reference No. E-051-2008/0-PCT-02], status: converted;
- Canadian Patent Application No. 2,720,363, filed April 15, 2009, titled “Composition and methods for delivering inhibitory oligonucleotides”, [HHS Reference No. E-051-2008/0-CA-04], status: pending;
- United States Patent Application No. 12/988,148, filed March 8, 2011, titled “Compositions and methods for delivering inhibitory oligonucleotides” [HHS Reference No. E-051-2008/0-US-07], status: issued as Patent No. 8,703,921;
- United States Patent Application No. 14/220,726, filed March 20, 2014, titled “Compositions and Methods for delivering inhibitory oligonucleotides” [HHS Reference No. E-051-2008/0-US-08], status: issued as Patent No. 9,415,116; and
- United States Patent Application No. 15,204,789, filed July 7, 2016, titled “Compositions and Methods for delivering inhibitory oligonucleotides” [HHS Reference No. E-051-2008/0-US-11], status: pending.

The patent rights in these inventions have been assigned to the government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to the use of Licensed Patent Rights for the following: “Treatment of pancreatic cancer by targeting regulatory T cells using complexes or fusion molecules comprising inhibitory nucleic acids, a nucleic acid binding moiety and a targeting polypeptide, wherein the targeting polypeptide contains either the TARC/CCL17 or RANTES/CCL5 cell surface receptor ligand.”

Despite significant attractiveness of anti-sense oligonucleotide technology, its clinical application has been precluded by a lack of methods for targeted delivery and transduction of primary immune cells in vivo. Novel complexes and methods for delivering inhibitory nucleic acids to cells in a targeted and efficient manner are disclosed in this invention. The complexes and methods are based on utilizing a cell surface receptor targeting ligand and a nucleic acid binding domain that binds an inhibitory nucleic acid, to efficiently deliver the inhibitory oligonucleotide to the cell that expresses the cell surface receptor targeting ligand. The compositions can be used to silence gene expression in a cell or to deliver agents to a target cell, thereby treating or preventing a disease or disorder.

The invention has broad utility as the cell surface receptor targeting ligand could be any molecule such as, cytokines, chemokines, antibodies or growth factors, that binds to a unique cellular receptor or cell surface antigen. Cytokines are small secreted proteins which mediate and regulate immunity, inflammation, and hematopoiesis. Chemokines are a family of small cytokines that are secreted by cells. They act on their target cells by binding specific membrane receptors. TARC/CCL17 and RANTES/CCL5 are examples of chemokines whose receptors are CCR4 and CCR5, respectively.

The complexes of this invention could inactivate immune cells by delivering oligonucleotides. For example, the TARC-nucleic acid binding domain complex referred to as TARC-arp, has been shown to deliver si-FoxP3 oligonucleotide into CCR4-expressing cancer cells that will specifically only inactivate FoxP3 expression. Chemokine-based gene silencing can be therapeutically used to modulate immune cells and improve outcome of diseases, such as by inactivating Tregs to block cancer escape and metastasis.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR Part 404. The prospective Exclusive Patent License will be royalty bearing and may be granted unless within fifteen (15) days from the date of this published notice, the National Cancer Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.

Complete applications for a license in the prospective field of use that are filed in response to this notice will be treated as objections to the grant of the contemplated Exclusive Patent License Agreement. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the *Freedom of Information Act*, 5 U.S.C. 552.

Dated: June 27, 2017

Richard U. Rodriguez,
Associate Director
Technology Transfer Center
National Cancer Institute

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